

REMARKS

1. The Examiner has objected to claim 30 for an informality. The word “and” was missing from the claim recitation. Correction to the claim has been made. The addition of the word does not add new matter or change the meaning or scope of the recitation of the claim as previously presented.

2. In view of the Appeal Brief filed by Applicants on July 24, 2009, the Examiner has reopened prosecution on this application and hereby entered claims 1, 11, 30 and 38. Thereafter, the Examiner has newly rejected claims 1, 11, 30 and 38 as being anticipated by Kapundu, et al., under 35 USC §102(b). In response to the newly applied rejection, Applicants are given the statutory option of filing a new Notice of Appeal or responding to the Office Action under 37 CFR §1.111. In their duty to further prosecution on its merits, Applicants hereby reply to the Office Action under 37 CFR §1.111.

We begin by presenting the relevant portions of the prosecution history of this application to date and follow with rebuttal arguments to the Examiner’s rejection.

A. The Kapundu, et al., reference was first raised by the Examiner in her Office Action of October 25, 2002, to the parent application. It was then raised in the RCE non-final Office Action of May 30, 2007. However, in the subsequent Office Action of March 28, 2008, the prior art rejection of the claims were based on another reference and Kapundu, et al., was not mentioned. In subsequent communications with the Examiner, namely a telephonic interview, Applicants’ proposed amendments likely would have placed the application in condition for allowance. The Examiner noted that the only condition against allowance would be the discovery of prior art that reads on the claimed invention. *See* Interview Summary Record of

July 24, 2008. However, the Examiner issued an Advisory Action on August 21, 2008, stating that the amendment was not entered because “Applicant’s insertion of the limitation “fractionated” would require further search and/or consideration¹²²”. See Note 3 of the Advisory Action, August 21, 2008. Applicants filed an Appeal Brief on May 22, 2009, on several grounds, including the fact that the term “fractionated” was suggested by the Examiner in the Office Action of March 28, 2008, that initiated the telephonic interview, and the Applicants’ reliance on the Examiner’s explicit statements made in the Interview Summary Record. Kapundu, et al., is not mentioned in any of these communications.

Applicants respectfully traverse the Examiner’s rejection and contend that the present Office Action is outside the scope of examination practices. While reopening of prosecution provides the Examiner a procedural mechanism to enter the claims, newly rejecting them on Kapundu, et al., is questionable as the amendments to the claims were addressed by the Examiner in the Telephonic Interview and the subsequent Advisory Action, neither of which mention the Kapundu, et al., reference. Furthermore, Applicants note that the Examiner presents the same inherency arguments (see rebuttal arguments below) that she had presented in her Office Actions prior to March 28, 2008, and ceased to continue thereafter. Such practices do not further prosecution and fail to provide Applicants the full and bona fide examination practices to which they are entitled.

Additionally, please note that the current Office Action makes no mention of the prior art rejection of the Office Action of March 28, 2008. Based on the prosecution history, it is the Applicants’ strong position that the omission of the Kapundu, et al., reference in the March 28, 2008, Office Action, and the omission of the Okunji, et al., reference in the November 16, 2009, Office Action are explicit showings that both references have been overcome. This is the

standard and accepted prosecution practice before the USPTO. Thus, it is the Applicants' position that the claims are now in condition for allowance.

B. The present rejection now states that the previously presented Kapundu, et al., reference, which discloses hydrolyzed methanolic powdered seed extract of *Napoloneae imperialis*, anticipates these claims as "the claim-designated plant comprises saponin....the claim-designated functional effect is considered inherent to the extract taught by Kapundu, because the source of the plant, the particular plant material from the source plant and the solvent used in the making of the plant extract taught by Kapundu are one and the same as disclosed by Applicant." See Examiner's Office Action of November 16, 2009 at 4.

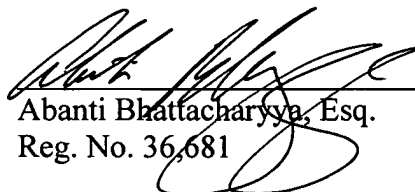
Applicants respectfully traverse the rejection. In order to invoke the standard of inherency, there must be a basis in fact and/or technical reasoning to reasonably support that the allegedly inherent characteristic flows from the teachings of the prior art. See MPEP §2112. Applicants have consistently maintained that the Examiner has failed to meet her burden under this standard. For example, Applicants' 132 affidavit discusses and distinguishes Kapundu, et al., in detail, specifically the point that Kapundu, et al., is strictly dependant upon the hydrolyzed seed extracts of *N. imperialis*. This is counterintuitive, and consequently counterproductive to the novel and unobvious characteristics of the present invention. To note: "the saponins were first hydrolyzed before isolation and chemical identification of the constituents...The product of hydrolysis is simpler, yielding low molecular weight compounds, less polar, less complex structurally and easy to handle... In contrast [sic]only naturally occurring pharmacologically active compounds were pursued...rather than hydrolyzed products....present knowledge on *N. imperialis* indicated that the major constituents of this plant are the saponins....saponin contents

have been reported to vary depending on factors (discussing geographic location)...saponin distribution among the organs of a plant may vary considerably (citing as example the variation in saponin concentration in marigold flowers varies significantly from that of the roots)....Our work on *Dracaena* species revealed that very high saponin content are found mostly in the seeds.” See Applicant’s §132 affidavit at 6. Note also that Applicants specifically discuss the problems associated with hydrolysis of saponins as taught by Kapundu, et al. These include complications with artifact formation, low yields, low selectivity and difficulty with structure elucidation. See *id* at 8. These factual distinctions have been repeatedly raised in rebuttal arguments by Applicants during prosecution. However, the Examiner has not addressed these distinctions in her rebuttal arguments. Instead, the Examiner has continued to provide factually unsupported conclusions such as those identified above. Such a rejection is without merit and continues to fail to meet the required burden of the inherency standard. Without the substantive factual basis required to meet the burden of inherency, the Examiner cannot sustain any prior art inherency standard rejection. Therefore, Applicants respectfully submit that the prior art rejection is overcome for the reasons stated in A and B above. Therefore, Applicants respectfully solicit that the present claims be placed in condition for allowance.

Please send all correspondences to: Elizabeth Arwine, Esq.; Office of the Staff Judge Advocate; U.S. Army Medical Research and Materiel Command; 504 Scott Street, Fort Detrick, MD 21702-5012; Attn: MCMR-JA (Ms. Arwine). Please direct any questions regarding this case to Ms. Abby Bhattacharyya, Esq., at (410) 964-9553.

Sincerely,

March 16, 2010
Date


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Reg. No. 36,681